

REMARKS

Claims 1-30 are pending and stand rejected. Applicant believes that claims 1-30 distinguish over the cited art and respectfully requests reconsideration and withdrawal of the current rejections.

Claim Rejection - 35 U.S.C. § 103

Claims 1-30 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. US2003/0065361 to Dreyfuss ("Dreyfuss") in view of U.S. Patent No. 5236,431 to Gogolewski et al. ("Gogolewski").

The Examiner states that

Dreyfuss discloses in Figures 1-7 a tissue fixation device, comprising an elongate body 108 formed of a biocompatible material (page 3, section 0038, lines), having an outer surface (FIG. 5), a proximal end (Fig. 5), a distal end (FIG. 5), a longitudinal axis (FIG. 5), an internal cavity 136, extending into the body forming an opening in the proximal end (FIG. 5) of the body, the cavity terminating proximal to the distal end (FIG. 5), at least one opening (117, 118) formed in the outer surface of the body, the opening is in fluid communication with the internal cavity (FIG. 5).

The Examiner recognizes that Dreyfuss fails to disclose the use of a bioresorbable material, but argues that that use of a bioresorbable material would have been obvious in view of Gogolewski.

Applicant respectfully disagrees.

Claim 1 is directed to a bioimplantable tissue fixation device comprising an elongate body formed of a biocompatible, bioresorbable material. The body has an outer surface, a proximal end, a distal end and a longitudinal axis extending therethrough. An internal cavity extends into the body from an opening in the proximal end of the body and terminates proximal to the distal end. At least one opening is formed in the outer surface of the body, each of the at least one openings being in fluid communication with the internal cavity such that the internal cavity is able to accept a treatment material for delivery external to the outer surface of the body through the at least one opening.

As mentioned above, the claimed device is preferably formed of a bioresorbable material, which will degrade over time after it is implanted into a patient to affix tissue. Where the device is used to affix a prosthetic ligament or tendon, the use of bioresorbable materials allows natural tissue to gradually replace the fixation device as the device degrades, resulting in a stronger and more durable prosthetic. The limitation directed to a bioresorbable material does not merely recite an intended use. Rather, it sets forth a structural feature of the claimed device and must be given weight.

Dreyfuss is fundamentally different as it teaches a suture anchor for anchoring sutures in bone that is “made of a biocompatible *metal*, preferably a *titanium alloy*,”¹ (emphasis added) materials which clearly are not bioresorbable. Dreyfuss specifically teaches the use of non-bioresorbable materials such as metals as a way to overcome what it alleges to be the drawbacks of biodegradable suture anchors. For example, Dreyfuss comments unfavorably on biodegradable suture anchors, stating that “the suture eyelet can degrade rapidly, causing the suture to become detached from the anchor prematurely.”²

As such, Dreyfuss not only fails to disclose biocompatible materials, but actually teaches away from their use. The Examiner merely cites Gogolewski and alleges, that it would have been obvious to modify Dreyfuss to include Gogolewski’s teaching of a bioresorbable material. The only argument made by the Examiner to support this wholesale modification of Dreyfuss is that it would “allow the fixation device to degrade in the body over a period of time.” However, this ignores the fact that Dreyfuss *wants to avoid a bioresorbable material*. This is a classic and improper application of hindsight.

The Examiner fails to apply the legal requirement that the prior art be shown to provide sufficient motivation to one of ordinary skill in the art to combine the references. Thus, in combining references in an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The Federal Circuit has stated:

¹ Dreyfuss at Paragraph 15.

² Dreyfuss at Paragraph 13.

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court’s conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 (“strict observance” of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”).

In re Dembiczak, 50 USPQ2d 1614 (Fed. Cir. 1999).

The Examiner has not provided clear and particular reasons for modifying the device of Dreyfuss to include a bioresorbable material, but simply concludes that the requisite motivation exists to “allow the fixation device to degrade in the body over a period of time.” In addition to ignoring that Dreyfuss actually teaches away from such a bioresorbable material, this type of conclusory statement falls well short of the requirement to specifically identify the reasons why one of ordinary skill in the art would be motivated to combine the references.

Accordingly, claim 1, and the claims the depend therefrom, distinguish over the cited references. Applicant respectfully requests withdrawal of the rejection in view of Dreyfuss and Gogolewski.

Claims 25-30 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. US2003/0065361 to Dreyfuss (“Dreyfuss”) in view of U.S. Patent No. 5236,431 to Gogolewshi et al. (“Gogolewski”), and further in view of U.S. Patent Application Publication No. 2004/0225292 to Sasso et al. (“Sasso”).

Independent claim 25 is directed to a method for attaching a tissue graft to bone. The method includes forming a bone tunnel into bone and providing a tissue fixation device in the form of an elongate member having a longitudinally oriented channel formed therein that extends from an opening in a proximal end thereof, the tissue fixation device having at least one opening formed in a sidewall thereof that is in fluid communication with the channel. A tissue graft is positioned in a portion of the bone tunnel and the tissue fixation device is inserted within the bone tunnel to secure the tissue graft there. The method also includes the step of injecting a treatment material into the channel of the tissue fixation device to enable the material to be secreted through the at least one opening to a region external to the sidewall of the tissue fixation device.

None of the cited references disclose or suggest the steps of forming a bone tunnel into bone, positioning a tissue graft in the bone tunnel, and inserting a tissue fixation device within the bone tunnel to secure the graft therein. The references also fail to disclose such steps in combination with the step of injecting a treatment material into the channel of the tissue fixation device to enable the material to be secreted through the at least one opening to a region external to the sidewall of the tissue fixation device.

Instead, Dreyfuss, as mentioned above, is directed to a *suture anchor*. The suture anchor is driven into hard tissue and a suture is threaded around an exposed loop. Nowhere does Dreyfuss suggest fixing a tissue graft by placing the graft into a bone tunnel and securing the graft by inserting a tissue fixation device into the bone tunnel. Similarly, Gogolewski teaches a fixation pin but does not suggest using the fixation pin according to the claimed method. In

particular, Gogolewski's fixation pin is not used to fix a tissue graft within a bone tunnel. Sasso also lacks any suggestion of fixing a tissue graft within a bone tunnel. Instead, Sasso is directed to bone anchors or bone screws that can be implanted in a vertebral body to connect upper and lower portions of the vertebral body.


Accordingly, claim 25, and the claims the depend therefrom, distinguish over the cited references. Applicant respectfully requests withdrawal of the rejection of these claims in view of Dreyfuss, Gogolewski, and Sasso.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. However, should any outstanding issues remain, Applicant asks that the Examiner please contact the undersigned Attorney for Applicant.

Dated: May 4, 2006

Respectfully submitted,

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